510(k) Summary

SEP 02 2010

K101310

Manufacturer: Theken Spine, LLC
1800 Triplett Blvd
Akron, OH 44306

Device Trade Name: Theken Spine Vu aPOD Intervertebral Body Fusion Device

Contact: Glenn Stiegman
Vice President, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
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Date Prepared: August 5, 2010

Classification: §888.3080, Intervertebral body fusion device

Class: II

Product Code: MAX

Indications For Use:
When used with the bone screws, the Theken Spine Vu aPOD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft material.

When used with the SpinPlate, the Theken Spine Vu aPOD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft material. When used with the SpinPlate, the Theken Spine Vu aPOD Intervertebral Body Fusion Device is intended for use with supplemental fixation such as the Coral Spinal System or the BodyForm Thoracolumbar Fixation System.

The Theken Spine Vu aPOD Intervertebral Body Fusion Device, when used with bone screws, is a stand alone device. If the Theken Spine Vu aPod Intervertebral Body Fusion Device is used with the SpinPlate then additional supplemental fixation, which has been cleared by the FDA for use in the lumbar spine, must be used to augment stability. The SpinPlate and bone screws are not intended to be used together. This device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

Device Description:
The Vu aPOD Intervertebral Body Fusion Device consists of lumbar spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Vu aPOD spacers are manufactured from PEEK OPTIMA LT1 polymer per ASTM F2026 while the bone screws and SpinPlate are comprised of Titanium alloy (Ti-6Al-4V ELI) per ASTM F136. Radiographic markers present with the Vu aPOD spacers are comprised of tantalum per ASTM F560. The Vu aPOD Intervertebral Body Fusion Device is for lumbar spinal use at one or two contiguous levels from the L2-L3 to L5-S1 disc levels.

Predicate Device(s):
The Vu aPOD Intervertebral Body Fusion Device was shown to be substantially equivalent to previously cleared devices, including the Theken Spine Vu aPOD System (K080822), Titan Spine Endoskeleton TA (K080615), Spinal Elements Lucent Magnum + (K083475), and LDR Spine ROI-A (K082262), and has the same indications for use, design, and function.

Performance Standards:
Preclinical testing has been performed per ASTM F2077 (static axial compression, static compression-shear, static torsion, dynamic axial compression, dynamic compression-shear, expulsion) and ASTM F2267 (static subsidence) indicating that the Vu aPOD Intervertebral Body Fusion Device is substantially equivalent to predicate devices.

Conclusion:
Sufficient information, including extensive testing, has been presented to demonstrate the Vu aPOD Intervertebral Body Fusion Device is substantially equivalent to predicate devices with the same indications, intended use, and technological features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

Theken Spine, LLC
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Glenn Stiegman
Vice President, Regulatory Affairs
1331 H Street NW, 12th floor
Washington, DC 20005

Re: K101310
Trade/Device Name: Vu a·POD Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: August 12, 2010
Received: August 13, 2010

Dear Mr. Stiegman:

This letter corrects our substantially equivalent letter of September 2, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

SEP 02 2010

510(k) Number (if known): K101310

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101310